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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,416	05/19/2005	Jaume Pinol Ribas	Q-87778	7473
23373	7590	09/17/2008		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER SHAHNAN SHAH, KHATOL S	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 09/17/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,416

Applicant(s)

RIBAS ET AL.

Examiner

Khatol S. Shahnan-Shah

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-29 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. Applicants' amendment of 6/12/2008 has been acknowledged. . Claims 13 and 19 have been amended. Specification multiple pages has been amended.
2. Declaration under 37 C.F.R. 1.132 of Laura Ferrer Soler filed 6/12/2008 has been acknowledged

Status of Claims

3. Claims 13-29 are pending in this application. Claims 1-12 have been canceled in a previous amendment. Claims 13-17 and 19 are under consideration. Claims 18 and 20-29 have been withdrawn from further consideration.

Election/Restrictions

4. Applicants argue that Reimer et al do not disclose a mutant strain which comprises a mutation in at least one region of A gene for apxI and apxII. The office does not agree with applicants' arguments as mentioned in the previous action. Assuming if the applicants assertion that Reimer et al do not disclose a mutant strain were true, the claims still lack unity of invention because each group of I-IV as mentioned in the restriction mailed 10/02/2007 has a special technical feature that is not required for the other groups.

The special technical feature of group I is a strain of *Actinobacillus pleuropneumoniae* APP.

The special technical feature of group II is a strain of *Actinobacillus pleuropneumoniae* CECT 5985.

The special technical feature of group III is a strain of *Actinobacillus pleuropneumoniae* CECT 5994.

The special technical feature of group IV is a method of obtaining an organism.

The requirement is still deemed proper and is therefore made FINAL. Claims 13-17 and 19 are under consideration. Claims 18 and 20-29 are withdrawn from further

consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Objections Withdrawn

5. Objection to the specification made in paragraph 3 of the office action mailed 2/13/2008 has been withdrawn in view of applicants' amendments of 6/12/2008.

Rejections Withdrawn

6. Rejection of claims 13-17 under 35 U.S.C. 101 made in paragraph 8 of the office action mailed 2/13/2008 has been withdrawn in view of applicants' amendments of 6/12/2008.
7. Rejection of claim 19 under 35 U.S.C. 112 first paragraph made in paragraph 10 of the office action mailed 2/13/2008 has been withdrawn in view of declaration under 37 C.F.R. 1.132 of Laura Ferrer Soler filed 6/12/2008.

Rejections Maintained

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Rejection of claims 13-17 under 35 U.S.C. 102 (b) made in paragraph 12 of the office action mailed 2/13/2008 is maintained.

The rejection was as stated below:

Claims 13-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by MacInnes et al. US 6,019,984

Claims are drawn to an immunogenic, non-hemolytic *Actinobacillus pleuropneumoniae* strain comprising a mutation in a least in one region of the *apxIA* gene and optionally a mutation in a least in one region of the *apxIIA* gene.

MacInnes et al. teach immunogenic, non-hemolytic *Actinobacillus pleuropneumoniae* strains comprising a mutation in a least in one region of the *apxIA* gene and optionally a mutation in a least in one region of the *apxIIA* gene (see abstract and claims and columns 1-4). MacInnes et al. teach deletion mutations, *apxIA* and *apxIIA* (see claims 6-12 and column columns 3 and 4 and figures). As to product of claim 19 and product of MacInnes et al. they are indistinguishable (see columns 13-14). MacInnes et al. teach do not explicitly teach nucleotides 886 to 945 of *apxIA* gene, however, such limitation would inherent in the full sequence of *apxIA* taught by MacInnes et al. The prior art anticipates the claimed invention.

Applicants' arguments filed 6/12/2008 have been fully considered but they are not persuasive.

The applicants argue:

- MacInnes is directed to a method of preparing a vaccine in which the microorganism has at least one RTX toxin which is substantially cell-associated. However, "substantially cell-associated" as defined at column 8 in MacInnes is not a mutation. Also, even though MacInnes discloses a modified App strain, only the B and D genes is modified (column 30 and claims 6-12 of MacInnes). MacInnes does not disclose at least one mutation in the transmembrane domain of the A gene of *apxI* or optionally *apxII*.

MacInnes teach transposon mutants of different strains and APX toxins from 12 different serotypes of *Actinobacillus pleuropneumoniae* strains (see figures 3, 16, 17, 18 and 19). MacInnes also teach that outer membrane proteins of *Actinobacillus pleuropneumoniae* can be altered by changing the growth conditions (see column 22).

10. Rejection of claims 13, 14, 15, 17 and 19 under 35 U.S.C. 102 (b) made in paragraph 13 of the office action mailed 2/13/2008 is maintained.

The rejection was as stated below:

Claims 13, 14, 15, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Prideaux et al. US 6, 0472,183 B2.

Claims are drawn to an immunogenic, non-hemolytic *Actinobacillus pleuropneumoniae* strain comprising a mutation in a least in one region of the apxI gene and optionally a mutation in a least in one region of the apxIIA gene.

Prideaux et al. teach immunogenic, non-hemolytic *Actinobacillus pleuropneumoniae* strains comprising a mutation in a least in one region of the apxI gene and optionally a mutation in a least in one region of the apxIIA gene (see abstract and claims and columns 1-2). Prideaux et al. teach deletion mutations, apxIA and apxIIA (see claims 1-4 and column columns 3 and 4). As to product of claim 19 and product of Prideaux et al. they are indistinguishable (see columns 8, 20 and examples 5-6). The prior art anticipates the claimed invention.

Applicants' arguments filed 6/12/2008 have been fully considered but they are not persuasive.

The applicants argue:

- Prideaux is directed to a modified APP strain comprising an RTX A gene and an inactivated RTX C gene, so that the C gene is mutated. Prideaux does not disclose at least one mutation in the transmembrane domain of the A gene of apxI or optionally apxII.

Prideaux et al. teach mutated A gene of apxI (see example 4 , column 14) wherein apxI A gene and a Kanamycin resistance gene linked to T5 promoter was resulted in transformants which were Kanamycin resistant and produced white colonies.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is 571-272-0863. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Khatol Shahnan-Shah. B.S.,
Pharm, M.S.
Biotechnology Patent Examiner
Art Unit 1645
September 15, 2008

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645